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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/701,698

11/05/2003

Ricardo Blank

N-32769A

7089

1095

7590

06/30/2006

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

BOGART, MICHAEL G

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

<b>Application No.</b> 10/701,698		<b>Applicant(s)</b> BLANK ET AL.	
<b>Examiner</b> Michael G. Bogart		<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/04/04; 08/10/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restriction***

This application contains claims directed to the following patentably distinct species:

- I. an opening means that comprises a cutting member protruding from the connector device as claimed in claims 3 and 6-9.
- II. an opening means comprising a trigger member that acts upon a leverage system on the frame-like member of the laminated packaging system, claims 4 and 5.

The species are independent or distinct because species I is a cutting member or spike contained entirely on the connector device while species II has a trigger member that acts on a leverage member on the box itself.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 2 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Gary Lobel on 20 June 2006 a provisional election was made without traverse to prosecute the invention of I, claims 1-3 and 6-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4 and 5 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the valve means, dosing means and pump set must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: --Connector Device for an Enteral Administration Set--.

Applicants are advised that the title at line 1 of the specification includes a typographical error.

### ***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 10 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Quinn et al. (US 4,895,275; hereinafter “Quinn”).

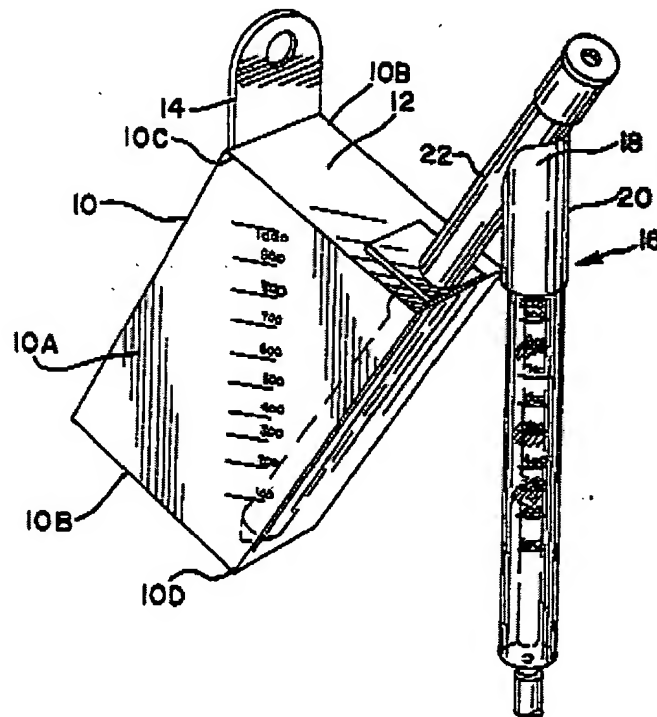
Quinn teaches a connector device (16) and a laminated paper packaging system (10) comprising:

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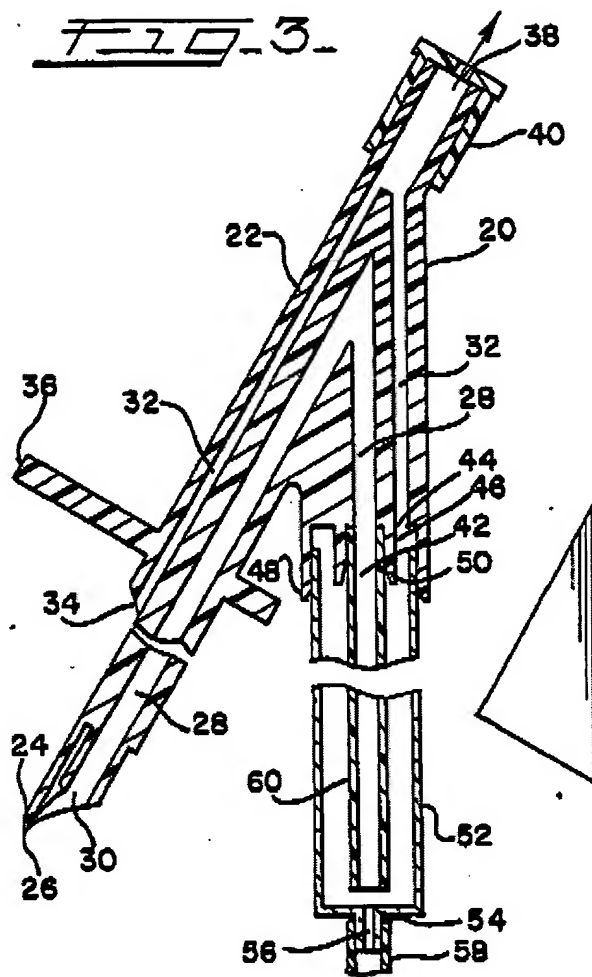
means (54) capable of fitting to an enteral administration set (58),

means (22) adapted to fit to the laminated paper packaging system (10),

a passageway (30) adapted to allow the flow of a composition contained in the laminated paper packaging system (10) from the laminated paper packaging system to the enteral administration set (10) through the connector device (abstract)(page 10, lines 11-24)(see figures 1 and 3, infra).



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Regarding claims 10 and 12, Quinn teaches a vent (22, 32) and a visualization tube (52) in fluid communication with the vent (22), the vent (22, 32) including a spike (26).

Claims 1-3, 6-9, 13, 17 and 18 are rejected under 35 U.S.C. § 102(a) as being anticipated by Kawaguchi *et al.* (CA 2 432 623 A1; hereinafter "Kawaguchi").

Kawaguchi teaches a connector device (12) and a laminated paper packaging system (20) comprising:

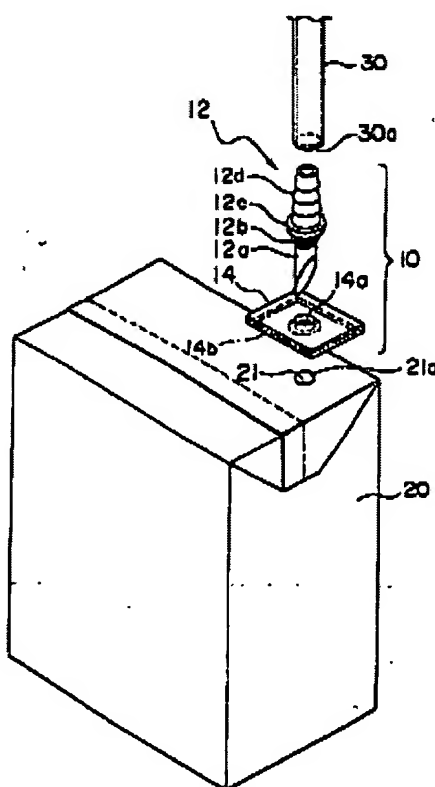
means (12d) capable of fitting to an enteral administration set (30),

means (12a) adapted to fit to the laminated paper packaging system (20),

a passageway (12g) adapted to allow the flow of a composition contained in the laminated paper packaging system (20) from the laminated paper packaging system to the enteral administration set (30) through the connector device (abstract)(page 10, lines 11-24)(see figure 1, *infra*).

Regarding element 30 being interpreted as an enteral administration set, this is a functional limitation. Apparatus claims must be structurally distinguishable over the prior art. MPEP § 2114. Tubing (30) can be used as an enteral set or feeding tube.

FIG. 1

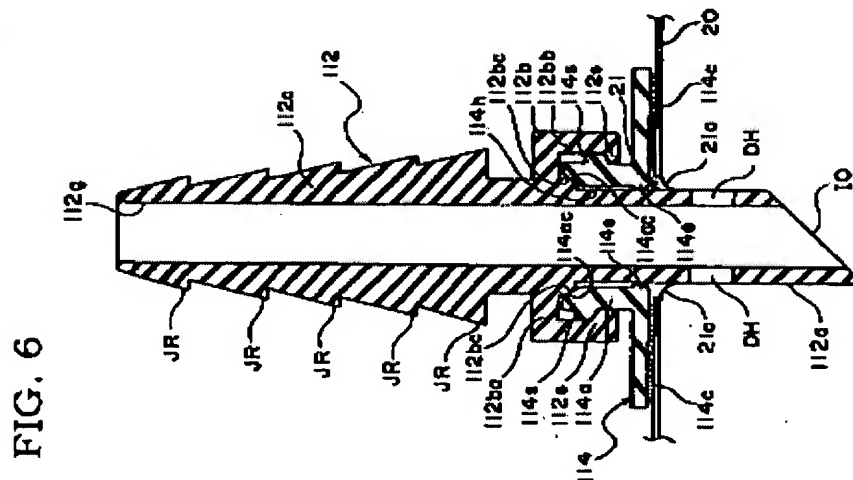


Regarding claim 2, Kawaguchi teaches that the connector (112) comprises a rigid tube part (112) capable of attachment of a feeding line of an enteral administration set (30), the tube part (112) containing part of the passageway (12g) for the composition to be administered, and



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wherein the means (112a) adapted to fit to the laminated paper packaging system (20) comprise an internally threaded portion (112b, 112s) adapted to be screwed onto a corresponding outwardly threaded portion (114s) of a frame-like member (114) of the laminated paper packaging system, and wherein the connector device further comprises means (112a) for opening of the laminated paper packaging system (20) upon screwing the connector device (112) onto the frame-like member of the laminated paper packaging system (20)(page 11, lines 9-12)(see figure 6, infra).



Regarding claim 3, Kawaguchi teaches that the means for opening the laminated paper packaging system comprises a cutting member (12a, 112a) protruding downwards from the connector device (12, 112) towards the laminated paper packaging system (20) for cutting the laminated paper packaging system (20) when the connector (12, 112) is screwed onto the frame-like member (114)(abstract).

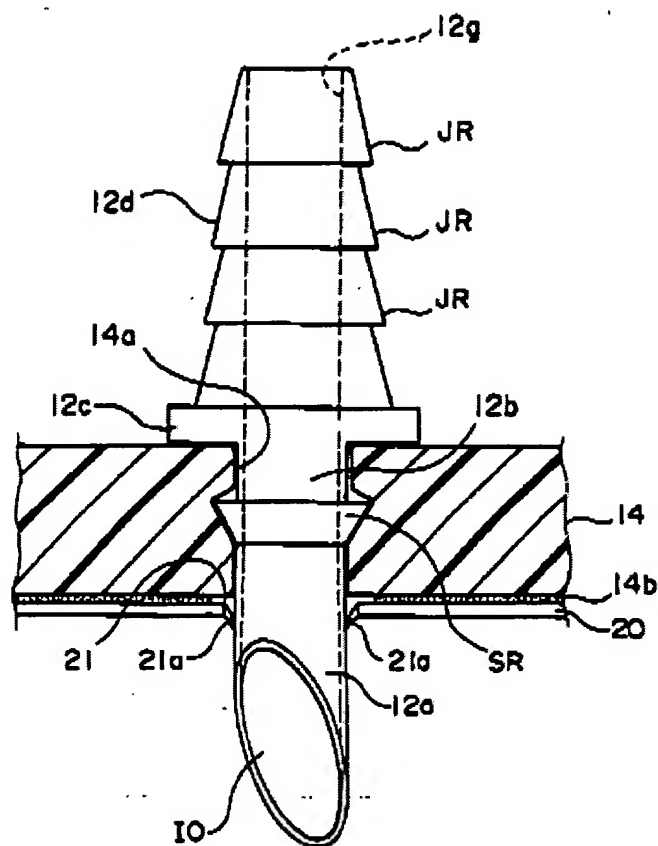
Regarding claim 6, Kawaguchi teaches the means (12d) that is capable of fitting to an enteral administration set (30) comprises a rigid tube part (12) for attachment of a feeding line

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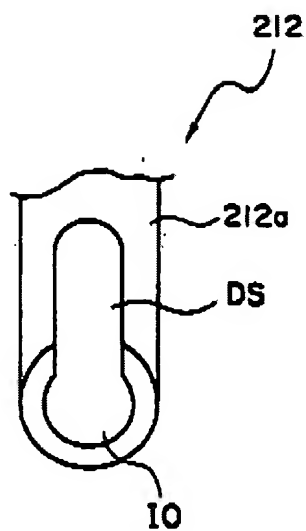
of the enteral administration set (30), the tube part (12) containing a part of the passageway (12g) for the composition to be administered, and wherein the means (12a) adapted to fit to the laminated paper packaging system (20) comprises a spike (12a) for penetrating into the interior of the laminated paper packaging system (20) as well as an attachment means (14) for fixedly attaching the connector device (12) to the laminated paper packaging system (20), the spike (12a) comprising a continuation of that part of the passageway (12g), which is contained in the tube part (12), into the interior of the laminated paper packaging system (20).

Regarding claim 7, Kawaguchi teaches that the attachment means (14) for fixedly attaching the connector device (12) to the laminated paper packaging system (20) comprises a rim (14) having an upper surface facing towards the laminated paper packaging system, an adhesive layer (14b) being provided on the upper surface for attaching the connector (12) to the laminated paper packaging system (20) upon penetration of the spike (12a) and pressing of the upper surface of the rim (14) with the adhesive layer (14b) against the laminated paper packaging system (20).

Regarding claim 8, Kawaguchi teaches that the attachment means for fixedly attaching the connector device (12) to the laminated paper packaging system (20) comprises two rims (12c, 14b) extending in parallel around the spike (14a) axially spaced from each other at a predetermined distance, that rim (14b) located nearer to the point of the spike (12a) being made from a flexible material while that rim (12c) located farther from the point of the spike (14a) being made from a rigid material (see figure 2, *infra*).



Regarding claim 9, Kawaguchi teaches that the spike (212a) is slotted (DS) along a part of its length (see figure 8, *infra*).



Regarding claim 13, Kawaguchi teaches a prefabricated enteral administration system comprising an enteral administration set (30) and a connector device (12) non-releasably connected to the enteral administration set (30).

Regarding claims 17 and 18, Kawaguchi teaches a kit comprising prefabricated enteral administration system (30) according and a laminated paper packaging system (20) containing a composition capable of being enterally administered to a patient.

Claims 1-3, 6-9, 13, 17 and 18 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kawaguchi *et al.* (US 2004/0104246 A1; hereinafter “’246”).

’246 is the U.S. equivalent of Kawaguchi. All of the 102 rejections under Kawaguchi apply in the same manner under ’246.

### ***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Quinn as applied to claims 1, 10 and 12 above, and further in view of D'Alo *et al.* (US 4,888,008; hereinafter "D'Alo").

Quinn does not teach a valve.

D'Alo teaches a spiked connection component having a vent including a valve (9) to control the passage of fluid through the vent.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the valve of D'Alo to the vent of Quinn to prevent backflow of fluids into the vent.

Claims 14 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi as applied to claims 1-3, 6-9, 13, 17 and 18 above, and further in view of Quinn and Schafer (US 5,993,422 A).

Kawaguchi does not teach a pump unit or means of controlling administration of fluid to a user of that device.

Quinn teaches the use of a TETRA BRIK type container as an enteral feeding device.

Schafer teaches a device for dosing medical fluids which includes a pump (2)(abstract).

At the time of the invention, it would have been obvious to modify the fluid container of Kawaguchi so that it functions as a enteral device as taught by Quinn, and to further add the dosing means and pump of Schafer in order to provide automation of the complete system.

Claims 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi as applied to claims 1-3, 6-9, 13, 17 and 18 above, and further in view of Quinn and Hindricks (US 3,001,525).

Kawaguchi does not teach an intermediate bag.

Quinn teaches the use of a TETRA BRIK type container as an enteral feeding device.

Hendricks teaches parenteral equipment that includes an intermediate bag (1) for mixing solutions.

At the time of the invention, it would have been obvious to modify the fluid container of Kawaguchi so that it functions as a enteral device as taught by Quinn, and to further add the intermediate bag of Hendricks in order to provide a means of reconstituting solutions.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart  
20 June 2006

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

